Remarks:

Reconsideration of the application is requested.

Claims 1 to 109 remain in the application. Claims 1 to 6, 10 to 21, 24 to 29, 40 to 60, 65 to 67, 70 to 72, 75 to 77, 80 to 82, 85 to 87, 90 to 92, 95 to 97, 100 to 102, and 105 to 108 are subject to examination and claims 7 to 9, 22, 23, 30 to 39, 61 to 64, 68, 69, 73, 74, 78, 79, 83, 84, 88, 89, 93, 94, 98 to 109 have been withdrawn from examination.

Restriction Requirement

The Examiner is correct with regard to the traversal of claims 100, 101, 103, 105, 106, and 108 and, therefore, the traversal of these claims is hereby withdrawn.

Drawings

On page 2 of the above-identified final Office action, the drawings have been objected to. More specifically, the Examiner states that "the support member connected to the graft without touching the stents or touching one of the stents must be shown."

The Examiner, again, did not specify which claims these features relate to but it is assumed that the objection relates to claims 26, 27, and 28:

26. The vascular repair device according to claim 25, wherein said support member is connected to said graft body without touching said inner stents.

27. The vascular repair device according to claim 25, wherein said support member is connected to said graft body to touch at least one of said inner stents.

28. A vascular repair device, comprising:

a tubular graft body having first and second ends;

a structural framework having at least three stents, two of said stents being connected to said tubular graft body adjacent said first end, said two stents being separated from one another on said graft body to define an outer stent and an inner stent, a third of said stents being connected to said tubular graft body adjacent said second end; and

a longitudinal support member having two ends and being connected to said graft body between said inner stent and said third stent without touching said inner stent and said third stent.

It is respectfully believed that FIG. 1 already shows these features. First, it is noted that the inner stents of claims 25 to 28 can be any of the stents between lines 52 and 52' in FIG. 1. Page 24, lines 23 and 24, of the specification of the instant application provides that the "stents 20 are sewn either to the exterior or interior surfaces of the graft sleeve 10." Further, page 35, lines 12 to 16, provides that the "longitudinal support member 40 is, preferably, sewn to the graft sleeve 10 **in the same way as the stents 20**. However, the longitudinal support member 40 **is not sewn directly to any of the stents 20** in the proximal portions of the graft. **In other words, the**

longitudinal support member 40 is independent of the proximal skeleton formed by the stents 20." (Emphasis added by applicants.)

Clearly, the support member 40:

does not touch inner stents 28, 28' (see claim 26);

does touch at least one of the inner stents 20 disposed between stents 28, 28' (see claim 27); and

does not touch an inner stent 20, 28, 28' (for example) and a third stent 23, 25 (see claim 28).

Therefore, applicants respectfully believe that all of the features are illustrated in the drawings and no new drawing figure is needed.

"Relatively parallel" is referred to herein as an extent that is more along the longitudinal axis 11 of the stent graft 1 than along an axis perpendicular thereto. P. 33-34

Substantive Rejections Under Section 102 and 103

In the first paragraph on page 4 of the above-identified Office action, claims 1, 2, 5, 6, 10, 11, 14, 15 to 17, 20,

21, 24 to 29, 40 to 42, 44 to 47, 49, 51, 55, 57, 59, 65 to 67, 70 to 72, 75 to 77, 85 to 87, 90 to 92, and 95 to 97 have been rejected as being fully anticipated by United States Patent Publication No. 2003/883,005 to Van Schie et al. (hereinafter "Van Schie") under 35 U.S.C. § 102.

The rejection has been noted and some of the claims have been amended in an effort to even more clearly define the invention of the present application. Support for the changes is found in FIG. 1, for example, of the specification of the present application.

Before discussing the prior art in detail, it is believed that a brief review of the invention as claimed, would be helpful. Claim 1, as amended, calls for, *inter alia*, a vascular repair device, including:

> a tubular graft body <u>having a longitudinal axis</u>; and
>
> a <u>curved</u> <u>longitudinal</u> <u>support member</u> having a <u>centerline parallel to the longitudinal axis</u> and <u>being substantially symmetrical with respect to the longitudinal axis</u>.

Claim 15, as amended, calls for, *inter alia*, a vascular repair device, including:

> a tubular graft body <u>having a longitudinal axis</u>;
>
> a structural framework having at least two stents connected to the tubular graft body; and

> a curved longitudinal support member connected to the graft body independent of the structural framework, having a centerline parallel to the longitudinal axis, and being substantially symmetrical with respect to the longitudinal axis.

The symmetry of the support member in claims 1 and 15 is with respect to the longitudinal axis -- which applicants submit is the same as the "centerline" used in the original claim 1. There is no difference between the two terms as used in original claims 1 and 15. Nonetheless, these claims have been amended to describe the axis of the graft body and the centerline of the support member. This wording makes even more clear than before.

Symmetry in the context of the present application is defined as having a portion of the support member that is not always along the centerline thereof -- in other words, the support member 40 of the invention of the present application has portions at a distance from the centerline and those portions are symmetrical with respect to the longitudinal axis.

Van Schie, in complete contrast, always has its supporting material 8 extend along a single axis -- in other words, the Van Schie support member extends straight along the longitudinal axis of the stent. See Van Schie at FIGS. 1 and 2 and paragraph 0045 (Note: anchor wire 70 in FIG. 7 is removed from the stent as set forth in paragraph 0056). Thus,

Van Schie cannot be said to anticipate the features of claims 1 or 15.

Claim 16, as originally supplied, calls for, *inter alia*, a vascular repair device, including:

> a tubular graft body;
>
> a longitudinal support member having two ends, at least one of the ends having a curved longitudinal extremity.

This claim provides that the end of the support member is curved.

The examiner contends that the ends 9, 10 are "rounded" and, therefore, the material 8 is has a "curved longitudinal extremity." There is no disclosure or suggestion in Van Schie to support this conclusion, however. In fact, only the opposite conclusion can be supported. Van Schie provides that reference numerals 9 and 10 point to the separate "fastening" and "joining" devices that connect the elastic material 8 to the prosthesis. Accordingly, the features described with numerals 9 and 10 are not a part of the material 8. Instead, they are separate and cannot be considered as the material 8.

No embodiment of the supporting feature of Van Schie has a **longitudinal extremity** that is curved. Thus, Van Schie cannot be said to anticipate the features of claim 16.

Claims 20, 25, and 28 have similar features that will not be repeated below. Claim 20, as originally supplied, calls for, *inter alia*, a vascular repair device, including:

> a tubular graft body having a proximal end and a distal end;
>
> a structural framework having at least two pairs of stents each respectively connected to the graft body adjacent the proximal end and the distal end, the stents of each of the pairs of stents being separated from one another at the graft body to define a respective outer stent and a respective inner stent; and
>
> a longitudinal support member connected to the graft body and extending between:
>
> at least the inner stent of a first of the two pairs of stents; and
>
> at least the outer stent of a second of the two pairs of stents.

Claim 25, as originally supplied, calls for, *inter alia*, a vascular repair device, including:

> a curved longitudinal support member having two ends and being connected to the graft body between both of the inner stents of the two pairs of stents.

Claim 28, as originally supplied, calls for, *inter alia*, a vascular repair device, including:

> a structural framework having two stents connected to a tubular graft body adjacent a first end to define an outer stent and an inner stent and a third stent

connected to the tubular graft body adjacent a second end; and

a longitudinal support member connected to the graft body between the inner stent and the third stent without touching the inner stent and the third stent.

Simply put, the support member of the present invention **ends prior to** at least one stent of the structural framework.

Van Schie discloses no embodiment where a longitudinal member extends only between the inner stents or the outer stents. In every Van Schie embodiment, the longitudinal member extends past at least a part of the extremity stents. With regard to claim 25, Van Schie does not show (or even suggest) having a longitudinal support member extending no further than the two inner stents of the two pairs of stents. With regard to claim 28, Van Schie does not show or suggest a longitudinal support member extending no further than one of the two inner stents on one end and a third stent on the other end. Thus, Van Schie cannot be said to anticipate the features of claims 20, 25, or 28.

It is accordingly believed to be clear that no reference fully anticipates the features of claims 1, 15, 16, 20, 25, or 28. Claims 1, 15, 16, 20, 25, and 28 are, therefore, believed to be patentable over the art. The dependent claims are believed

to be patentable as well because they all are ultimately dependent on claim 1, 15, 16, 20, 25, or 28.

In the paragraph on pages 4 to 5 of the above-identified Office action, claims 1 to 6, 10 to 21, 24 to 29, 40 to 60, 65 to 67, 70 to 72, 75 to 77, 80 to 82, 85 to 87, 90 to 92, and 95 to 97 have been rejected as being obvious over United States Patent No. 6,099,558 to White et al. (hereinafter "White") in view of United States Patent No. 6,464,719 to Jayaraman under 35 U.S.C. § 103.

As will be explained below, it is believed that the claims were patentable over the cited art in their original form and, therefore, the claims have not been amended to overcome these references.

Before discussing the prior art in detail, it is believed that a brief review of the invention as claimed, would be helpful. Claim 1 calls for, *inter alia*, a

Claim 1, as amended, calls for, *inter alia*, a vascular repair device, including:

> a curved longitudinal support member <u>being substantially symmetrical with respect to said longitudinal axis</u>.

Claim 15, as amended, calls for, *inter alia*, a vascular repair device, including:

> a curved longitudinal support member connected to said graft body independent of said structural framework, having a centerline parallel to said longitudinal axis, and being substantially symmetrical with respect to said longitudinal axis.

Claim 16, as originally supplied, calls for, *inter alia*, a vascular repair device, including:

> a longitudinal support member having two ends, at least one of said ends having a curved longitudinal extremity.

Claim 18, as originally supplied, calls for, *inter alia*, a vascular repair device, including:

> a structural framework having at least two stents each respectively connected to the tubular graft body adjacent a proximal end and a distal end of the graft body and defining a separation distance therebetween; and
>
> a longitudinal support member shorter than the separation distance and being connected to the graft body between the two stents to form a gimbal at at least one of the proximal and distal ends of the graft body.

Claim 20, as originally supplied, calls for, *inter alia*, a vascular repair device, including:

> a structural framework having at least two pairs of stents each respectively connected to a graft body adjacent proximal and distal ends of the graft body, the stents of each of the pairs being separated from one

another at the graft body to define a respective outer stent and a respective inner stent; and

a longitudinal support member extending between:

at least the inner stent of a first of the two pairs of stents; and

at least an outer stent of a second of the two pairs of stents.

Claim 25, as originally supplied, calls for, *inter alia*, a vascular repair device, including:

a structural framework having at least two pairs of stents each respectively connected to a graft body adjacent proximal and distal ends of the graft body, the stents of each of the pairs being separated from one another at the graft body to define a respective outer stent and a respective inner stent; and

a curved longitudinal support member having two ends and being connected to the graft body between both of the inner stents of the two pairs of stents.

Claim 28, as originally supplied, calls for, *inter alia*, a vascular repair device, including:

a structural framework having at least three stents, two of the stents adjacent a first end of a graft body separated from one another to define an outer stent and an inner stent and a third stent connected adjacent a second end; and

a longitudinal support member having two ends and being connected between the inner stent and the third stent without touching the inner stent and the third stent.

As set forth below, neither Jayaraman nor White, nor a combination thereof disclose or suggest the configurations set

forth in *any* of the above claims. The differences between these claims and the two cited references will be discussed together in the paragraphs below.

Initially, it is noted that the Examiner admits "White et al. fail to disclose a longitudinal support member." Thus, White clearly is missing a required element of each of the above claims. In an attempt to make up for this clear deficiency and complete the rejection, the Examiner must *add* a feature of Jayaraman to White. Specifically, the Examiner states that "Jayaraman teaches (Fig. 8) a longitudinal support member 53 . . ." To support this combination, the Examiner merely states: "It would have been obvious to one of ordinary sill in the art to use curve longitudinal support members as taught by Jayaraman in the stent graft of White et al. such that it provides more support to the vessel walls and assist in expansion." Office action at page 5. No further statements or proof is given at all.

It is well settled that almost all claimed inventions are but novel combinations of old features. The courts have held in this context, however, that when "it is necessary to select elements of various teachings in order to form the claimed invention, we ascertain whether there is any suggestion or motivation **in the prior art** to make the selection made by the

applicant". *Interconnect Planning Corp. v. Feil*, 227 USPQ 543, 551 (Fed. Cir. 1985) (emphasis added). "Obviousness can not be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination". *In re Bond*, 15 USPQ2d 1566, 1568 (Fed. Cir. 1990). "Under Section 103 teachings of references can be combined **only** if there is some suggestion or incentive to do so." *ACS Hospital Systems, Inc. v. Montefiore Hospital et al.*, 221 USPQ 929, 933, 732 F.2d 1572 (Fed. Cir. 1984) (emphasis original). "Although a reference need not expressly teach that the disclosure contained therein should be combined with another, the showing of combinability, in whatever form, must nevertheless be **'clear and particular.'"** *Winner Int'l Royalty Corp. v. Wang*, 53 USPQ2d 1580, 1587, 202 F.3d 1340 (Fed. Cir. 2000) (emphasis added; citations omitted); *Brown & Williamson Tobacco Corp. v. Philip Morris, Inc.*, 56 USPQ2d 1456, 1459 (Fed. Cir. Oct. 17, 2000). Applicants respectfully believe that there is no "clear and particular" teaching or suggestion in Jayaraman to incorporate the features of White, and there is no teaching or suggestion in White to incorporate the features of Jayaraman.

In establishing a *prima facie* case of obviousness, it is **incumbent upon the Examiner** to provide a reason why one of ordinary skill in the art would have been led to modify a

prior art reference or to combine reference teachings to arrive at the claimed invention. *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Int. 1985). To this end, the requisite motivation must stem from some teaching, suggestion, or inference in the prior art as a whole or from the knowledge generally available to one of ordinary skill in the art and not from the applicants' disclosure. See, for example, *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1052, 5 USPQ2d 1434, 1439 (Fed. Cir. 1988), *cert. den.*, 488 U.S. 825 (1988). The Examiner has not provided the requisite reason why one of ordinary skill in the art would have been led to modify Jayaraman or White or to combine Jayaraman's and White's teachings to arrive at the claimed vascular repair device invention.

The Examiner has the burden for satisfying the above requirements. But, the Examiner has not shown the requisite motivation from some teaching, suggestion, or inference in Jayaraman or White or from knowledge available to those skilled in the art.

A critical step in analyzing the patentability of claims pursuant to 35 U.S.C. § 103 is casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and

the then-accepted wisdom in the field. See *In re Dembiczak*, 175 F.3d 994, 999, 50 USPQ2d 1614,1617 (Fed. Cir. 1999). Close adherence to this methodology is especially important in cases where the very ease with which the invention can be understood may prompt one "to fall victim to the insidious effect of a hindsight syndrome wherein that which only the invention taught is used against its teacher." *Id.* (quoting *W.L. Gore & Assocs. Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553, 220 USPQ 303, 313 (Fed. Cir. 1983)).

Applicants respectfully believe that any teaching, suggestion, or incentive possibly derived from the prior art is only present with hindsight judgment in view of the present application. "It is impermissible, however, simply to engage in a hindsight reconstruction of the claimed invention, using the applicant's structure as a template and selecting elements from references to fill the gaps. . . . The references **themselves** must provide some teaching whereby the applicant's combination would have been obvious." *In re Gorman*, 18 USPQ2d 1885, 1888 (Fed. Cir. 1991) (emphasis added). Here, no such teaching is present in the cited references.

Jayaraman does not have stents, let alone have the two stents required by the above-mentioned claims. Jayaraman does not even relate to prostheses that use stents or, especially, z-

stents. Accordingly, there cannot be any motivation to use the technology of Jayaraman in a z-stent graft such as White.

The Examiner contends that the S-shaped connecting pieces 53 of Jayaraman would "provide more support to the vessel walls and assist in expansion" if added to White. This, however, is not correct. There would be no assistance in the expansion of the White stent graft if the connecting pieces 53 of Jayaraman were added to White. In fact, the opposite is true, as any relatively rigid pieces attached to the graft tube of White would not "assist" in expansion. At best, there would be no affect on expansion and, at worse, it would hinder expansion.

Jayaraman clearly discloses that many of the connecting pieces 53 must be disposed about the circumference of the tubular body. There is no suggestion to use only one of the connecting pieces 53 in Jayaraman in any way and, especially, there is no hint or suggestion in White to make such a drastic change in the Jayaraman device. In fact, if one were to add multiple connecting pieces 53 to White (which is what is actually disclosed by Jayaraman), the resulting hypothetical stent graft would be significantly rigid about its longitudinal axis and would, therefore, *not be able to be implanted in curved vessels*! Such a hypothetical combination, therefore, would *defeat White's intended purpose*.

The Examiner cited FIG. 8 of Jayaraman for the feature that is added to White to form the combination rejection. It is significant to note that there is nothing to show or suggest in Jayaraman that the FIG. 8 prosthesis could ever function as a stent graft or even relate to a stent graft because there is no force applied by the connecting piece 53 that could ever assist in keeping the lumen of the material fabric tube 51 open after being implanted in a vessel. As such, it is respectfully believed that the combination of these two different features cannot be supported.

Claims 1 and 15 provide that the support member is substantially symmetrical with respect to a longitudinal axis of the device. White has no support members (see Office action at page 4, last line). As can be clearly seen in every figure of Jayaraman, the two extreme ends of the connecting pieces 53 end are always on the same side. Therefore, with respect to a longitudinal extent of the connecting piece 53, there is no way that the connecting piece 53 is symmetrical. See FIGS. 1, 3, 4, 7, and 8.

The Examiner contends on page 5, lines 8 to 11:

> Regarding the limitations that the support is symmetrical to the centerline of the graft, it is being interpreted that the middle of the graft is the

> centerline and thus half of the support is on one side and the other half on the opposite side. The support members [53] can also be said to be [be] symmetrical with respect to a centerline through itself." (Emphasis added by applicants.)

This statement is not only unsupported, it is contrary to the disclosure and meaning of "symmetrical" set forth in the present application. Further, the claims set forth a relationship that the support member is symmetrical with respect to the "longitudinal axis" of the graft body. Simply put, in the exemplary embodiments that relate to the claims of the present application, a part of the curved longitudinal support member is on one side of the centerline thereof and of the longitudinal axis and another part of the support member is on the other side, and these part are symmetrical with respect to the longitudinal axis. The Examiner seems to be trying to mischaracterize this disclosure towards a meaning that the support members are symmetrical about a *transverse* centerline "through itself" (i.e., through a line that is *orthogonal to* the longitudinal extent of the connecting pieces 53. However, use of the word "longitudinal" in the claims of the present application requires the symmetry to be with respect to the longitudinal extent and not the transverse extent.

The Examiner contends with regard to claim 16 that the connecting pieces 53 have "looped ends 55." As set forth

above, these ends are merely rounded. They do not have and are not "curved longitudinal extremit[ies]" as set forth in claim 16. The specification of the present application at page 37 provides:

> the end of the longitudinal support member loops 47 back upon itself such that the end of the longitudinal support member along the axis of the stent graft is not sharp and, instead, presents an exterior of a circular or oval shape when viewed from the ends 12, 14 of the graft sleeve 10. Such a configuration substantially prevents the possibility of tearing the vessel wall and also provides additional longitudinal support at the oval shape by having two longitudinally extending sides of the oval 47.

There is a difference between "rounded" and curved. As "curved" is used in the present application, it means that the end traverses a curve. In contrast, the ends of 53 are straight with rounded edges. The rounded ends of the connecting pieces 53 are not curved and do not traverse a curve and, therefore, cannot suggest the curved extremities disclosed in claim 16. The Examiner contends that the part labeled "55" in Jayaraman is such a curved end. It is respectfully submitted that this reference numeral merely identifies the "holes" in the end of the pieces 53 for receiving a suture to connect the piece 53 to the graft. See Jayaraman at col. 4, line 24.

Claims 18, 20, 25, and 28 include features where a longitudinal support member has a length smaller than a distance between two stents to create a gimbal as in claim 18, for example. Neither Jayaraman nor White disclose or even suggest such a feature and, therefore, a combination of the two also do not suggest such a feature.

Clearly, the combination of Jayaraman and White do not suggest the vascular repair device as recited in claims 1, 15, 16, 18, 20, 25, or 28 of the present application.

It is accordingly believed to be clear that no reference or combination thereof suggest the features of claims 1, 15, 16, 18, 20, 25, or 28. Claims 1, 15, 16, 18, 20, 25, and 28 are, therefore, believed to be patentable over the art. The dependent claims are believed to be patentable as well because they all are ultimately dependent on claim 1, 15, 16, 18, 20, 25, or 28.

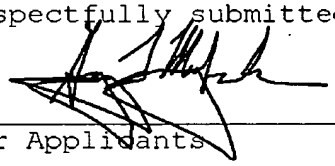
In view of the foregoing, reconsideration and allowance of claims 1 to 6, 10 to 21, 24 to 29, 40 to 60, 65 to 67, 70 to 72, 75 to 77, 80 to 82, 85 to 87, 90 to 92, 95 to 97, 100 to 102, and 105 to 108 are solicited.

In the event the Examiner should still find any of the claims to be unpatentable, counsel would appreciate receiving a telephone call so that, if possible, patentable language can be worked out.

If an extension of time for this paper is required, petition for extension is herewith made.

The extension fee for response within a period of one (1) month pursuant to Section 1.136(a) in the amount of $120.00 in accordance with Section 1.17 is enclosed herewith.

Respectfully submitted,



For Applicants

Gregory L. Mayback
Reg. No. 40,719

GLM:cgm

September 18, 2006

Gregory L. Mayback, P.A.
5722 S. Flamingo Road, #232
Fort Lauderdale, Florida 33330
Phone: 954.704.1599
Fax: 954.704.1588
greg@mayback.com
www.mayback.com